September 15, 2022

CTL Medical Corporation
% Dhaval Saraiya
Regulatory/Quality Consultant
Omni Strategic Solutions, LLC
700 Pennsylvania Ave SE
2nd Floor
Washington, District of Columbia 20003

Re: K213641
Trade/Device Name: MONDRIAN ALIF Cage with Supplementary Fixation Plate
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: September 6, 2022
Received: September 6, 2022

Dear Dhaval Saraiya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213641

Device Name
MONDRIAN ALIF Cage with Supplemental Fixation Plate System

Indications for Use *(Describe)*
The MONDRIAN ALIF Cage with Supplementary Fixation Plate System (MONDRIAN ALIF Cage) is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone.

The MONDRIAN ALIF Cage with Supplementary Fixation Plate System is intended for use with either two or four titanium alloy screws which are provided with the system. When used with screws and implants with lordotic angles ≤20°, the MONDRIAN ALIF Cage with Supplementary Fixation Plate System is a stand-alone interbody fusion device. If the physician chooses to use fewer than the number of screws compatible with the plate, then a supplemental spinal fixation system that is cleared for use in the lumbosacral spine must be used. Hyperlordotic cage offerings (>20°) require the use of a supplemental fixation system (e.g. facet screws or posterior fixation).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the MONDRIAN ALIF Cage with Supplemental Fixation Plate System 510(k) premarket notification.

Sponsor:

CTL Medical Corporation
Sean Suh
4550 Excel Pkwy
Ste 300
Addison, TX 75001

Contact Person:

Dhaval Saraiya
Omni Strategic Solutions, LLC.
Regulatory/Quality Consultant
Email: omniregsolutions@gmail.com

Date:

November 15, 2021

Subject Device:

Trade Name: MONDRIAN ALIF Cage with Supplemental Fixation Plate System

Common Name: Lumbar Intervertebral Fusion Device
Classification Name:
MAX – Intervertebral Fusion Device with Bone Graft, Lumbar (21 CFR 888.3080)
OVD – Intervertebral Fusion Device with Integrated Fixation, Lumbar (21 CFR 888.3080)

Predicate Device(s):

Primary Predicate:	K192863	MONDRIAN™ Lumbar Interbody Fusion Cage System	CTL Medical Corporation
Reference Device:	K160597	INDEPENDENCE® Spacers	Globus Medical Inc.

Purpose and Device Description:

The purpose of this submission is to request clearance for the new MONDRIAN ALIF Cage with Supplemental Fixation Plate System. The MONDRIAN ALIF Cage with Supplemental Fixation Plate System are anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals. The system is comprised of spacers, plates, screws and instruments to facilitate the installation of the implants. The spacers are manufactured from PEEK per ASTM F2026 and/or Titanium Alloy per ASTM F136, plates and screws are manufactured from Titanium Alloy per ASTM F136. The instruments are manufactured from Stainless Steel per ASTM F899. Implants and instruments will be provided in non-sterile configuration and will require steam sterilization prior to use.

Intended Use and Indications for Use:

The MONDRIAN ALIF Cage with Supplementary Fixation Plate System (MONDRIAN ALIF Cage) is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autograft bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone.

The MONDRIAN ALIF Cage with Supplementary Fixation Plate System is intended for use with either two or four titanium alloy screws which are provided with the system. When used with screws and implants with lordotic angles ≤20°, the MONDRIAN ALIF Cage with Supplementary Fixation Plate System is a stand-alone interbody fusion device. If the physician chooses to use fewer than the number of screws compatible with the plate, then a supplemental spinal fixation system that is cleared for use in the lumbosacral spine must be used. Hyperlordotic cage offerings (>20°) require the use of a supplemental fixation system (e.g. facet screws or posterior fixation).

Summary of Technological Characteristics:

- **The rationale for substantial equivalence is based on consideration of the following characteristics:**
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- **Intended Use:** The intended use is similar to the intended use cleared in K160597 and K192863.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in K160597 and K192863.
- **Materials:** The MONDRIAN ALIF Cage with Supplemental Fixation Plate implants are manufactured from PEEK per ASTM F2026 and/or Titanium Alloy per ASTM F136 and instruments are manufactured from Stainless Steel per ASTM F899 which are commonly used materials in orthopedic implants and instruments and similar to materials used in K160597 and K192863.
- **Design Features:** The design features for the MONDRIAN ALIF Cage with Supplemental Fixation Plate System implants and instruments are similar to those in currently marketed devices cleared in K160597 and K192863. The design differences have not identified any issues that would impact the safety and effectiveness of the device.
- **Sterilization:** The MONDRIAN ALIF Cage with Supplemental Fixation Plate implants and instruments are offered to the user in the non-sterile configuration. The non-sterile implants and instruments will be required to be steam sterilized by the user prior to use is similar to the devices cleared in K160597 and K192863.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Tests:**
  - Axial Dynamic Compression (per ASTM F2077)
  - Screw Push-Out Testing
  - Plate-Cage Disassembly Testing
- **Clinical Tests:**
  - N/A

Substantial Equivalence Conclusion:

The MONDRIAN ALIF Cage with Supplemental Fixation Plate System has shown to be substantially equivalent to the predicate device. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.